No.		名称		
MED 17	○	atrial flutter	first-line RF ablation vs. antiarrhythmic drug therapy	Sense of well being (pre-RF 2.0 +/- 0.3 vs. post-RF 3.8 +/- 0.5, p < 0.01) and function in daily life (pre-RF 2.3 +/- 0.4 vs. post-RF 3.6 +/- 0.6, p < 0.01) improved after ablation, but did not change significantly in patients treated with drugs.
21	○	ventricular tachycardia	catheter ablation therapy vs. amiodarone	Ablation also produced a greater increase in quality of life (2.78 versus 2.65 quality-adjusted life-years [QALYs]).
26	○	paroxysmal atrial fibrillation	AV junction ablation and DDDR/MS pacemakers vs. medical therapy vs. ablation and VVIR pacemaker	Follow-up over 18 weeks was at 6-week intervals and used quality-of-life questionnaires (Psychological General Well Being [PGWB], McMaster Health Index [MHI], cardiac symptom score). Changes in score from baseline were better with ablation and DDDR/MS pacing for PGWB (+12% versus +0.5%, P<0. 05). DDDR/MS was better than VVIR pacing for MHI (+5%, P<0.03).

○：Ablation または Ablation + pacemaker が抗不整脈より優れているとする評価

×：抗不整脈薬が優れているとする評価

（5）コストベネフィット

アブレーション治療のコストは amiodarone 治療より高いが、QALY を検討するとアブレーションの採用を正当化できるとした報告があった。

抄録 No.	評価	疾病名称	技術	コスト
21	○	ventricular tachycardia	catheter ablation therapy vs. amiodarone	In a hypothetical cohort of 10 000 patients, 5-year costs were higher for patients undergoing ablation compared with amiodarone therapy ($21 795 versus $19 075). Ablation also produced a greater increase in quality of life (2.78 versus 2.65 quality-adjusted life-years [QALYs]). This yielded a cost-effectiveness ratio of $20 923 per QALY gained for ablation compared with amiodarone. Results were relatively insensitive to assumptions about ablation success and durability. In less severe patients with good ejection fractions who suffer their first VT episode, the incremental cost-effectiveness ratio was $6028 per QALY gained. These cost-effectiveness ratios are within the range generally thought to warrant technology adoption.

○：Ablation または Ablation + pacemaker が抗不整脈より優れているとする評価

×：抗不整脈薬が優れているとする評価

H．その他

心房細動患者に対する房室間連結部の完全なアブレーションとモディフィケーションとの比較を行い、アブレーションが発作の頻度と心房細動の症状の大きさを減じるのに効果的

で、また、ＱＯＬの結果も良かったとした論文が見られた。他に、再発防止のためにibutilideとaminodaroneが同様に効果的だとしたもの、抗不整脈薬の再発防止効果を示したもの、アブレーションとflecainide注入が効果的としたもの、アブレーション適用患者の１％が血栓を併発し、その予防にheparineが効果ありとするもの、アブレーション後のペースメーカーの選択はDDDR/MSがVVIRより良さそうに見えるがアブレーション前の精密検査で心房細動発作の頻度と継続期間を評価しなければならないとしたものがそれぞれ１件あった。

抄録 No.	評価できる技術	疾病名称	技術	治癒性
MED 1	-	Atrial Fibrillation	Amiodarone vs. ibutilide	Immediate recurrences of AF were suppressed by amiodarone in 8 of 10 patients (80%), and by ibutilide in 9 of 15 patients (60%, p = 0.4). After crossover, immediate recurrence of AF was suppressed in 2 of 6 patients (33%) by amiodarone, and in 1 of 2 patients (50%) by ibutilide (p = 0.6).
2	antiarrhythmic drug therapy (+)	paroxysmal atrial fibrillation	antiarrhythmic drug therapy (+ vs. -) and ablation and pacing treatment	The drug arm patients had a 57% reduction in the risk of developing permanent atrial fibrillation (21% vs 37%, P=0.02). Evaluation after 12 months revealed similar quality of life scores and echocardiographic parameters in the two groups, but the drug arm patients had more episodes of heart failure and hospitalizations (P=0.05).
7	flecainide infusion (+)	atrial fibrillation	Catheter ablation and flecainide infusion (+) vs. (-)	During a mean follow-up period of 24 +/- 7.2 months, the recurrences of AF and atrial flutter in group B (42%) were significantly lower than those in group A (78%, p < 0.001), group C (92%, p < 0.001) and group D (92%, p < 0.001).
31	ablation	medically refractory atrial fibrillation	AVJ ablation with permanent pacing vs. AVJ modification	patients after complete AVJ ablation had a significantly greater improvement in general QOL and a significantly reduced frequency of major symptoms and symptoms during attacks (including palpitation, dizziness, chest oppression, blurred vision and syncope).
37	guided by the algorithm	Arrhythmia	guided by the algorithm vs. not guided by the algorithm	The successful ablation site could be predicted accurately in 18 (90%) of the 20 patients in group 2B. The radiofrequency pulses, ablation time, and fluoroscopic time were markedly reduced in Group 2B, mainly because of the omission of unnecessary mapping procedure in the right posteroseptal area in patients with "left atrio-left ventricular" fibers.
CCTR 1	-	atrial fibrillation and flutter	Mode switching (MS) DDDR pacing vs. VVIR pacing following AV node ablation	Prolonged irregular heart beat had a worse symptom score (0.5 v 1.2, p < 0.01) in the MS DDDR mode. But other symptom scores and general well-being scores were not significantly different. Exercise duration was greater (488 s v 380 s, p < 0.05) in those patients (n = 7) with P-waves on the day of exercise in MS DDDR.

5－3－4　ECMO

MEDLINE 14件、CDSR 2件、CCTR 2件　計18件のうち、呼吸障害を起こした新生児へECMOを適用した結果に関するものが7件、ECMOの機器の試験3件、併用薬剤に関するもの3件、他に界面活性剤投与2件などである。

A．呼吸障害を起こした新生児へのECMOの適用

（1）技術適用疾病

疾病名称は新生児の acute respiratory failure of babies, reversible lung disease, cardiorespiratory failure, acute respiratory distress syndrome であった。

（2）診断・治療能力

治癒結果は、7件全てが肯定的評価である。

抄録No	ECMOの評価	疾病名称	技術	治癒性
MED 2	○	acute respiratory failure of babies	ECMO vs. contemporary conventional care	The neonatal ECMO policy resulted in improved survival and a favourable outcome.
3	○	severe respiratory function (infants)	ECMO vs. conventional management	In addition to providing a survival advantage, ECMO did not worsen lung function in infants assigned to receive it. Indeed, their lung function appeared slightly better than that of infants treated conventionally.
6	○	severe respiratory failure in term babies	ECMO vs. conventional management	63 (68%) of the 93 infants randomised to extracorporeal membrane oxygenation survived to 1 year compared with 38 (41%) of the 92 infants who received conventional management.
9	○	cardiorespiratory failure in term infants	ECMO vs. concentional treatment	Thirty of 93 (32%) ECMO infants died before the age of 1 year and 54 of 92 (59%) of the infants in the conventional group died.
14	○	severe respiratory failure in mature newborn infants	ECMO vs. conventional management	Death rates differed between the two trial groups; 30 of 93 infants allocated ECMO died compared with 54 of 92 allocated conventional care.
CDSR 1	○	respiratory failure of neonatal infants	ECMO vs. conventional ventilatory support	All four trials showed a strong benefit of ECMO on mortality (RR 0.44; 95% CI 0.31 to 0.61), especially for babies without congenital diaphragmatic hernia (RR 0.33, 95% CI 0.21 to 0.53). Overall nearly half of the children had died or were severely disabled at four years of age, reflecting the severity of their underlying conditions.
CCTR	○	respiratory failure	ECMO vs. conventional	Death rates differed between the two trial groups; 30 of 93 infants allocated ECMO died compared with 54

2			management	of 92 allocated conventional care. The relative risk was 0.55 (95% CI 0.39-0.77; p = 0.0005), which is equivalent to one extra survivor for every three to four infants allocated ECMO.

○：対比療法に対し効果を認めた　△：有意な差を認めない　×：対比療法より治癒成績が悪かった　－：判断できない

（3） 安全性・信頼性

特に記載が無かった。

（4） 患者ＱＯＬ

抄録No	ECMOの評価	疾病名称	技術	QOL
MED 10	○	acute respiratory distress syndrome	ECMO vs. mechanical ventilation or healthy controls	Long-term survivors of ECMO-therapy reported significant reductions in physical functioning when compared with patients treated by mechanical ventilation alone (group I, -12.5%, p < 0.05) and with healthy controls (group II, -50%, p < 0.05) and showed a higher incidence of chronic physical pain (+5% and +24%, respectively, p < 0.05).

○：対比療法に対し効果を認めた　△：有意な差を認めない　×：対比療法より治癒成績が悪かった　－：判断できない

（5） コトベネフィット

新生児の呼吸不全に対するEMCOの経済的評価は２件の論文が言及しており、他の方法よりはコストイフェクティブだとしている。

抄録No	ECMOの評価	疾病名称	技術	コスト
6	○	severe respiratory failure in term babies	ECMO vs. conventional management	The estimated additional cost of extracorporeal membrane oxygenation per additional surviving infant without severe disability was 51 222 pounds and the cost per surviving infant with no disability was 75 327 pounds.
CDSR 1	○	respiratory failure of neonatal infants	ECMO vs. conventional ventilatory support	Based on economic analysis from the UK trial, the ECMO policy is as cost-effective as other intensive care technologies in common use.

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Ｂ．併用薬剤の評価

（1） 機器技術適用疾病

幼児の利尿作用に関する、カニューレ部の出血防止、アプロプリノールの副作用の３件である。

（２）診断・治療能力

ECMO 治療中の幼児の利尿作用がフロセミドとテオフィリンの複合投与により高まる。
ECMO 治療を受けている幼児のカニューレ部出血の止血剤として fibrin sealant は出血のリスク、出血量、出血時間を減少させた。
カニュレーション前とECMOの間に投与されるアロプリノールがプリン低下と尿酸生産を禁止し、再酸素付加とバイパス経由で回復した低酸素性新生児の血液注入の間、酸素遊離基の生産を減らすらしい、ということが分かった。

抄録No	併用薬剤の評価	疾病名称	技術	治癒性
MED 7	○	Infants receiving ECMO	theophylline, furosemide vs. placebo	Infants who received theophylline/furosemide had significantly higher urine flow rates than those who received placebo/furosemide on day 1 (11.8 +/- 4.6 vs 7.2 +/- 2.4 ml/kg/hr, $p < 0.01$).
11	○	bleeding at the cannulation site in neonates undergoing ECMO	fibrin sealant (+) vs. (-)	Fibrin sealant reduced the risk of bleeding, was associated with less shed blood, and was associated with shorter duration of hemorrhage. Further, control infants showed an increased bleeding risk with less depressed fibrinogen levels and prothrombin time elevations >18 seconds prior to ECMO.
12	○	progressive hypoxemia	Alloprinol vs. placebo	Hypoxanthine was higher in allopurinol-treated infants during the time of bypass studied ($p = 0.022$). Xanthine was also elevated ($p < 0.001$), and uric acid was decreased ($p = 0.005$) in infants receiving allopurinol. Similarly, urinary elimination of xanthine increased ($p < 0.001$), and of uric acid decreased ($p = 0.04$) in treated infants. No allopurinol toxicity was observed.

○：対比療法に対し効果を認めた　△：有意な差を認めない　×：対比療法より治癒成績が悪かった　－：判断できない

（３）安全性・信頼性

（４）患者ＱＯＬ

（５）コストベネフィット

特に記載が無かった。

Ｃ．機器の評価

3 件の抄録があった。運用性，規格の指標に関連したものとして、9 種類の ECMO の性能評価を行ったものがある。安定性について、新しい中空ファイバー膜式酸素加装置と従来機種との比較があった。治療結果には差がないが、新しい装置は、効率の良い酸素輸送と低い溶血率を有する。信頼性に関しては、コーティングしてないステンレス製熱交換器を持った新しい中空繊維膜 ECMO を使用する際の潜在的な問題を調べたものがある。高い膜内外圧力が持続して酸素付加性能が低下しているものもあり、あるものは交換が必要であったとしている。

抄録 No	疾病名称	技術	機器の評価結果
MED 1	-	Oxygenators: Maxima PRF Plus, Affinity, Forte, Affinity NT, Quantum, Optima, Capiox 1.8, Hilite and Quadrox	Best oxygen transfer : Quantaum, Affinity NT The Highest oxygen transfer/m2 : Quantum The Lowest shunt fraction (15%) : Maxima, Quantum, Affinity NT The Lowest pressure drop : Quadrox, Affinity NT The Highest pressure drop : Quantum, Capiox, Optima The most efficient Oxygenator : Quadrox The smallest performance factor : Maxima There are no difference in platelet drop and haemolysis.
8	undergoing coronary artery bypass grafting	new generation hollow-fibre membrane oxygenator (Spiral Gold) vs. the Univox Gold membrane oxygenator	During cardiopulmonary bypass, the Spiral group had a significantly lower pressure drop (26.9 +/- 8.2 vs 46.7 +/- 16.2 mmHg, p < 0.001). The Spiral group had significantly lower plasma free haemoglobin levels during all time periods of CPB compared to the Univox group. There were no differences in oxygen transfer between groups, but ventilation gas sweep rates and FiO2 levels were statistically lower in the Spiral group at two of the three sampling time periods.
13	-	hollow-fibre membrane oxygenators	there were several cases during which the high trans-membrane pressures persisted, resulting in decreasing oxygenator performance. In one such case, oxygenator change-out was required.

D．その他

界面活性剤投与については 2 件あり、いずれも重症度を減らし ECMO サポートを減らすことにも効果があるとしている。

抄録 No	評価	疾病名称	技術	治癒性
MED 4	-	Heart Diseases	ECMO vs. conventional treatment	In the control group, four showed minor histological changes. The other hearts were histologically normal. In the group treated

				with ECMO, four had multiple foci of micro-infarction throughout both ventricles and papillary muscles. There was variable thrombotic vascular occlusion. Three were normal.
5	Epsilon -aminocaproic acid の効果認めず	Intracranial hemorrhage in neonates treated with ECMO	epsilon-aminocaproic acid vs. placebo	There was no statistical difference in the incidence of significant ICH in patients who received EACA (23%) versus placebo (12.5%). Septic patients accounted for all of the ICH in the EACA group. Thrombotic complications (aortic thrombus and SVC syndrome) developed in two patients from the placebo group. There was no difference in thrombotic circuit complications between groups.
CDSR 2	surfactant administration は ECMO の使用を減らす	meconium aspiration syndrome	surfactant administration (+) vs. (-)	The meta-analysis supports a significant reduction in the risk of requiring extracorporeal membrane oxygenation (typical relative risk 0.64, 95% CI 0.46, 0.91 typical risk difference -0.17, 95% CI -0.30, -0.04). No difference was noted in overall mortality (typical relative risk 1.86 95% CI 0.35, 9.89, typical risk difference 0.02 95% CI -0.03, 0.07).
CCTR 1	surfactant administration は ECMO の使用を減らす	respiratory failure	surfactant (beractant) administration (+) vs. (-)	There was no difference in the incidence of severe complications. The need for ECMO therapy was significantly less in the surfactant group than in the placebo group ($p = 0.038$); this effect was greatest within the lowest oxygenation index stratum (15 to 22; $p = 0.013$).

5－3－5　IABP

MEDLINE 10 件の論文があり、いずれも心筋梗塞、及び冠状動脈疾患に関するものである。

（1）技術適用疾病

acute myocardial infarction, cardiogenic shock complicating acute myocardial infarction, postcardiotomy dysfunction, coronary artery disease, valvular heart disease

（2）診断・治療能力

CABG 前の IABP 使用について 4 件の試験があり、いずれも効果を認めている。手術前の開始時間についてはセンシティブではないようである。

心筋梗塞の心原発性ショックに対し血栓溶解剤と IABP の併用に関しては 3 件の論文がみられ、いずれも効果ありとしている。

その他 IABP の長期化を防ぐためアンギオテンシン変換酵素抑制剤が効果的とする論文が見られた。また、PTCA 後の IABP 治療に臨床上の改善を認めないものが 1 件見られた。

抄録 No	IABP の 評価	疾病 名称	技術	治癒性、救命率・生存率
MED 1	○	cardiogenic shock complicating acute myocardial infarction	IABP (+) vs. (-) thrombolytic therapy (TT) vs. TT (-)	there was a significant difference in in-hospital mortality among the four treatment groups: TT + IABP (47%), IABP only (52%), TT only (63%), TT (-), IABP (-) (77%)　TT: 血栓溶解
2	○	Coronary Disease	preoperative IABP, 24 hours before 12 hours bufore 2hours before vs. IABP (-)	The complication rate for IABP was 8.3% (n = 5) without group differences. Cardiac index was significantly higher postoperatively (p<0.001) in patients with preoperative IABP treatment compared with controls. There were no significant differences between the three IABP subgroups at any time. The incidence of postoperative low cardiac output was significantly lower in the IABP groups (p<0.001).
3	○	postcardiotomy dysfunction, coronary artery disease, valvular heart disease	angiotensin converting enzyme inhibitor (captopril) vs. angiotensin (-)	Hospital mortality occurred in 31% of patients in group A and 14.5% in group B. Morbidity complications developed in 37% of patients in group A and 20% in group B.
4	○	Coronary Disease	preoperative IABP treatment vs. IABP (-)	The time on cardiopulmonary bypass was shorter in group 1, 86 versus 110 minutes (p = 0.006). There were no hospital deaths in group 1, but four deaths occurred in the control group (p = 0.049).

5	○	cardiogenic shock complicating acute myocardial infarction	IABP (+) vs. (-)	Early IABP use occurred in 62 patients (20%) and none in 248 (80%).Despite more adverse events in the early IABP group and more episodes of moderate bleeding, this cohort showed a trend toward lower 30-day and 1-year mortality rates
6	○	Coronary Disease	IABP, 1 day before CPB 1～2 hours before CPB vs. IABP (-)	The CPB-time was shorter in groups 1 and 2 88.7 +/- 20.3 min than in group 3 105.5 +/- 26.8 min, P < 0.001, while ischemia time did not differ. Hospital mortality was higher in group 3, 25% vs. 6% (groups 1 and 2).
7	△	acute myocardial infarction (AMI).	IABP (+) vs. (-)	There was no significant difference in the predefined primary combined end point of death, reinfarction, infarct-related artery reocclusion, stroke or new-onset heart failure or sustained hypotension in patients treated with an IABP versus those treated conservatively (28.9% vs. 29.2%, p = 0.95).
8	○	coronary artery disease	IABP (+) vs. (-)	Ischemia time was similar in both groups while CPB-time was shorter in the IABP group, p < 0.05. There were no hospital deaths in the IABP group, but 3 in the control group suffered postoperative low cardiac output. Nine patients (64%) in the control group required IABP support postoperatively, but only 20% of the patients in the IABP group had a shorter ICU stay, 2.4 +/- 0.9 vs. 3.4 +/- 1.1 days, p < 0.01.
10	○	Myocardial Infarction	IABP (+) vs. (-)	However, 3 weeks after myocardial infarction, the patients treated with IABP had a significantly higher frequency of TIMI flow grade 3, lower residual percent stenosis and larger minimal lumen diameter of the infarct-related artery than did the control subjects (74% vs. 32%, p < 0.05; 42 +/- 5% vs. 68 +/- 6%, p < 0.01; and 1.6 +/- 0.1 vs. 0.9 +/- 0.2 mm, p < 0.01, respectively).

○：対比療法に対し効果を認めた　△：有意な差を認めない　×：対比療法より治癒成績が悪かった　-：判断できない

（3）安全性・信頼性

（4）患者ＱＯＬ

特に記載が無かった。

（5）コストベネフィット

CABG 前の IABP 治療は IABP や ICU 使用時間を減らしコストベネフィシャルであるとしたもの、IABP 治療を受けた場合と受けない場合とのコスト比較は中間値でほぼ同等でコストを上げずに臨床上の利点があるとしたもの各１件が見られた。

抄録 No	IABP の評価	疾病名称	技術	コスト

6	○	Coronary Disease	IABP, 1 day before CPB 1～2 hours before CPB vs. IABP (-)	The IABP was removed after 3.1 +/- 1.0 days in group 3 vs. 1.3 +/- 0.6 days in groups 1 and 2, P < 0.001. In group 3, 11 patients required IABP postoperatively compared to only 4 patients in groups 1 and 2. ICU stay was shorter in groups 1 and 2--2.3 +/- 0.9 days vs. 3.5 +/- 1.1 days for group 3, P = 0.004. The procedure was cost-beneficial
9	○ コストを上げずに臨床上の利点	acute myocardial infarction	IABO (+) vs. (-)	Costs for patients who had IABP versus control patients were similar: mean $22,357 +/- $14,369 versus $19,211 +/- $8,414, median (25th and 75th percentiles) $17,903 ($15,787, $22,147) versus $17,913 ($15,144, $21,433), p = 0.45.

○：対比療法に対し効果を認めた　△：有意な差を認めない　×：対比療法より治癒成績が悪かった　-：判断できない

5－3－6　Percutaneous Cardiopulmonary Support

MEDLINE に２件の論文があったが、内容は以下の通りである。
Hemopump の臨床的、政策的、マーケティング的評価。心肺バイパスや PTCA と併用して有効であり、安価であるとしている。
ハイリスクの患者に対する、IABP と percutaneous cardiopulmonary bypass (PCPB)の効果を試験した。効果はおなじであるが、PCPB は血管合併症の発生確率が高く、輸血も必要であった。一方、IABP は挿入が容易であった。

（１）技術適用疾病

疾患名としては、cardiogenic shock, coronary artery である。

（２）診断・治療能力

抄録 No	PCPS の評価	疾病名称	技術	治癒性
MED 1	○	cardiogenic shock	Hemopump (+) vs. (-)	The Hemopump has demonstrated positive hemodynamic effects in patients. Laboratory and clinical studies have shown that the nonpulsatile axial flow generates flows of up to 4.5 L/min while maintaining adequate perfusion of other organs. In Europe, hemopumps have been used successfully to support coronary bypass and PTCA
2	×	coronary artery disease	percutaneous cardiopulmonary bypass vs. IABP	The primary success rate (95% vs 95%) and hospital mortality (5% vs 5%) were also similar in the two groups. Two patients required surgical exploration of the femoral artery and eight patients required blood transfusion in the PCPB group. IABP patients had no vascular complications and did not require blood transfusion

○：対比療法に対し効果を認めた　△：有意な差を認めない　×：対比療法より治癒成績が悪かった　-：判断できない

（３）安全性・信頼性

（４）患者ＱＯＬ

特に記載がなかった。

（５）コストベネフィット

Hemopump system はシンプルで安価であるとしている。

抄録 No	PCPS の評価	疾病名称	技術	コスト
MED 1	○	cardiogenic shock	Hemopump (+) vs. (-)	The Hemopump system is simple, inexpensive, and well tolerated by the blood elements.

5－3－7　Thrombolytic Therapy, Ultrasound

求める文献が得られなかった。

5－3－8　Heart Valve Bioprosthesis

Randomized Control Trial を条件に 1996 年以降発行された論文、MEDLINE 25 件、DARE 1 件、計 26 件の論文の要点を記す。

機器からみた試験（治療）目的をまとめてみると、heart(arotic、mitral、pulmonary) valve diseases に代表される心臓疾患に対し、autografts、homo(allo)grafts、conventional bioprosthesis valve を用いた valve replacement に関する論文である。
内容は、血行力学的評価を改善させ、寿命も長いことが予想されている stentless 生体弁と stented 生体弁を比較した論文が 8 件と最も多く、次に手順の複雑さが時間に関連した血行力学機能へ影響することが予想される autografts と homo(allo)grafts を比較した論文が 5 件、stentless な異種移植片（xenografts）と同種移植片（homografts）を比較した論文が 4 件、機械式弁と生体弁の比較が 4 件で残りはその他 5 件となっている。

疾病名称としては、aortic valve diseases 25 件、mitral valve diseases 2 件で、ほとんどが aortic valve replacement についての論文である。

A、 stentless と stented の比較
8 件の論文で使用された stentless bioprosthesis は Tront SPV が 4 件、Medtranic Freestyle が 1 件、stented bioprosthesis は CE(Carpentier Edwards SAV)3 件、Mosaic が 1 件であり、使用されるメーカーがほぼ固定されている。評価アイテムは血行運動性能（AoV 時間速度、transvalvalur gradient、ピーク流れ速度）、左心室肥大、弁開口部の減少等であり、詳細は後述する。
(1)技術摘要疾病
　aortic valve diseases 8 件
(2)診断・治癒能力
stentless 生体弁は stented のそれよりも血行力学的評価を改善させ、寿命も長いことが予想されていた。両者の臨床評価比較では血行力学的評価は注目に値するが、1 年間フォローしてみると特に差はないとする論文が 2 件、stentless の左心室の塊状物の早い退行を評価するのが 3 件、stentless の優れた transvalvalur gradient と左心室塊状物の早い退行を評価するのが 2 件、また 75 才以上の高齢者で左室の改良と長期の弁退化の視点から stentless を評価する論文が 1 件であった。

文献 No	結果	疾病名称	対比技術	治癒性
MED	△	aortic valve	stentless vs stented	The peak flow velocity was significantly lower in the stentless group, especially 1 week and 6 months after surgery.

2		diseases	bioprosthesis	Mean transvalvular gradient dropped significantly in stentless group and did not change in stented group. EOA did not change significantly in either of groups. AoV velocity time integral was increasing in stentless group. LV mass had fallen significantly in both groups but degree of mass reduction was comparable
MED 3	△	aortic valve deseases	stentless vs stented bioprosthesis valve	Although effective orifice areas increased, and mean and peak transvalvular gradients decreased in both groups over time, no differences were demonstrated between groups at 12 months. Similarly, although significant regression of left ventricular mass was accomplished in both groups over time, no differences were demonstrated between groups. Finally, Duke Activity Status Index scores of functional status improved in both groups over time;however, no differences were noted between groups at 12 months postoperatively.
MED 13	○	aortic valve diseases	stentless vs stent aortic bioprothesis	Hemodynamic performance in the first 24 hours showed no significant difference between the groups, but there was a trend for shorter ventilation time and shorter stays in the intensive therapy unit in the stentless group. Echocardiography showed superior transvalvular gradients in the stentless group at 1 week (mean 5.5+/-3.1 mm Hg cf. 8.9+/-2.5 mm Hg), and this difference was maintained at a mean follow-up time of 32 months (3.5+/-0.6 mm Hg cf. 6.3+/-0.6 mm Hg). Similar regression of left ventricular mass was seen in both groups at 6 months, but at 32 months, measurement in diastole showed a reduction of 38% (P<.01) in the stentless group compared with 20% (P = ns) in the stented group, and measurements in systole showed a 23% (P<.01) and 13% (P = ns) reduction, respectively.
MED 14	○	aortic valve diseases	Stentless vs conventional biological aortic valves	Postoperatively, left ventricular mass index was 213+/-77 g/m2 (stentless) compared with 202+/-72 (conventional group) g/m2 (NS), whereas after 6 months it was 141+/-41 g/m2 in the stentless and 170+/-43 g/m2 in the conventional group (P<.05).
MED 17	○	aortic valve diseases	stentless aortic valve vs conventional stented bioprothesis	106 patients received a stentless aortic valve (SAV), and 74 received a conventional stented bioprosthesis (CSB). At follow-up, all patients were in NYHA class 1 or 2. Baseline end-diastolic left ventricular posterior wall thickness was 15.6 (SAV) and 14.8(CSB) mm (P=NS) and decreased to 11. 8 (SAV) and 13.2 (CSB) mm (P<0.05) at 6 months. Left ventricular mass index was 213 and 202 g/m(2) at baseline (P=NS), whereas after 6 months, it was 141 (SAV) and 170 (CSB) g/m(2) (P<0.05).
MED 20	○	rtic lve seases	rtic mograft etless vs ented lve	he hemodynamic performance indices were much better for the mograft and stentless valves than for the stented one. he absolute left ventricular mass index reduction was greater in the mograft group compared with the Intact (p = 0.0004) and Toronto (p = 007) groups. The extent of percent left ventricular mass index duction was greater only in the homograft group versus Intact group = 0.005). he multilinear regression analysis showed that the only predictors of a rger percentage of left ventricular mass index reduction were the

				mograft type, a higher valve size index, and a higher preoperative left ntricular mass index.
MED 21	○	rtic lve seases	ancock vs entless optothesis	verall perioperative mortality was 5% in group A (low cardiac output in patients), and 8% in group B (low cardiac output in 1; major neurologic ent in 2). Follow-up is 97% complete (group A, 14.5+/-10 months; oup B, 18.5+/-12 months). One patient in group B died at 28 months of yocardial infarction. Actuarial survival at 12 and 24 months is 92% rsus 91% and 92% versus 81% for group A and group B, respectively. 6 months, patients in group A showed a peak transaortic gradient of +/-7 versus 20+/-9 mm Hg in group B. Progressive regression of left ntricular mass expressed as a percentage of preoperative value was .5% and 19% for group A and group B at 1 year postoperatively (not gnificant).
MED 23	○	aortic valve disease s	Stentless vs stented bioprothe sis	The stentless valve group had a longer ischaemic time (77.9 +/- 20.9 min v 60.9 +/- 21.9 min) and bypass time (101.7 +/- 27.1 min v 82.9 +/- 20.2 min). Using continuous cardiac output monitoring, no statistically significant differences were found in early haemodynamic indices although the stentless group required less inotropes and had a shorter ventilation time (16.1 +/- 4.2 hrs v 55.2 +/- 104.9 hrs) and intensive care stay (1.1 +/- 0.2 days v 4.6 +/- 8.3 days). Mean and peak aortic gradients one week postoperatively were lower in the stentless group (5.6 +/- 3 mmHg v 8.9 +/- 2.3 mmHg and 12.5 +/- 7.8 mmHg v 24.4 +/- 8.8 mmHg respectively). Magnetic resonance imaging at six months showed a 15% reduction in the end systolic muscle mass index in the stented group but a greater reduction of 29% in the stentless group.

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(3)安全性・信頼性

(4)患者 QOL

(5)コストベネフィット

特に記載なし

B、 autografts と homografts の比較

自家移植片（autografts）挿入の手順が複雑であり、血管のクランプ時間も長いため血行力学機能へ影響することが予想される。大動脈置換（AVR）で同種移植片（homograft）と比較した臨床評価では、自家移植片は回復や合併症、出血等では差はなく、むしろ同種移植の早い退化が問題であるとする論文が 2 件、両者差はなく自家移植片による AVR は安全であるとするのが 1 件、ロス手順の複雑さが右室機能に RV 縦機能障害を及ぼしているとする論文が 1 件、右室機能、弁退化、長期不整脈は優れており、術後初期・中期に至る現段階は評価できるとする論文が 1 件ある。

(1)技術摘要室病

aortic valve diseases 4 件、pulmonary valve diseases 1 件であった。

(2)診断・治癒能力

文献No	評価結果	疾病名称	対比技術	治癒性
MED 8	○	aortic valve diseases	ross operation vs aortic bioprosthesis, normal control	The hemodynamics of the aortic valve were very similar in Ross subjects and in control subjects at rest and during exercise. However, the indexed valve area of the pulmonary valve at rest was significantly (p < 0.001) lower in the Ross subjects (1.10 +/- 0.46 cm2/ m2) than in the control subjects (1.95 +/- 0.41 cm2/m2), resulting in higher (p = 0.004) mean gradients at rest (Ross: 9 +/- 7 mm Hg vs control: 2 +/- 1 mm Hg) and at peak exercise (Ross: 21 +/- 14 mm Hg vs control: 7 +/- 2 mm Hg).
MED 11	○	alotic valve diseases	pulmonary autograft vs aortic homograft	Autograft AVR required longer cross-clamp (41%) and bypass (43%) times, but did not result in significantly more bleeding, longer recovery or more complications. There were no autograft reoperations. There were no other valve-related events. At 48 months, actuarial survival and reoperation-free survival rates were 97.8% and 94.2% in group A, and 95.3% and 87.7% in group H (p = NS). Echocardiography showed near-perfect function in all autografts, but early signs of subclinical dysfunction in many homografts
MED 15	△	aortic valve diseases	pulmonary autograft vs aortic nomograft	One early death occurred in the homograft group, and 1 late (7 months) death occurred in the autograft group. One patient who received a pulmonary autograft was reoperated on for inflammatory pulmonary stenosis. One patient in each group was reopened for bleeding (both within 24 hours).Two patients in the autograft group had postoperative neurological weakness; they fully recovered over 2 months. Hospital stay, blood loss, incidence of perioperative arrhythmia, and markers of coronary ischemia were similar between the 2 groups. At 6-month follow-up (range, 1 to 12 months), left ventricular end-diastolic diameter was similar in both groups (homografts, 5.0+/-0.9 cm; autografts, 5.2+/-0.6 cm; P=NS), and no patient in either group had significant aortic valve dysfunction.
MED 16	×	aortic valve diseases	aortic homograft vs pulmonary autograht	In all patients, systolic excursion (SE) and both shortening and lengthening rates (SR and LR, respectively) were reduced postoperatively (P<0.05) homografts:SE 1. 5+/-0.4 versus 2.3+/-0.6 cm, SR 6.8+/-2.1 versus 9. 6+/-3.1 cm/s, LR 6.0+/-1.8 versus 8.9+/-3.0 cm/s; autografts:SE 1. 4+/-0.4 versus 2.2+/-0.4 cm, SR 5.8+/-3.0 versus 8.2+/-3.0 cm/s, LR 5.7+/-1.9 versus 8.5+/-3.7 cm/s). here were no differences between the 2 groups. Eighteen patients who had undergone either aortic homograft or pulmonary autograft surgery were studied between 6 and 35 months after surgery. RV volumes were assessed with the use of MRI in addition to echocardiographic RV long-axis measurements. Global volumes were increased to a similar amount in both groups (homografts: end-diastolic volume 145+/-34 mL, end-systolic volume 78+/-23 mL; autografts: end-diastolic volume 157+/-33 mL, end-systolic volume 89+/-25 mL; P=NS), whereas stroke volumes were maintained

				in both groups (homografts 67+/-15 mL, autografts 67+/-16 mL; P=NS). RV SE was depressed in both groups to a similar degree to that seen with the previous group (homografts 1.5+/-0.3 cm, autografts 1.4+/-0.2 cm).
MED 25	○	aortic valve diseases	pulmonary autograft vs homograft	No early or late deaths had occurred in this series at a mean follow-up time of 16 months (range 3 to 21 months). Two patients (one in each group) required reexploration for bleeding. No statistically significant differences were observed between the two groups with regard to ventilatory support (group A, mean 10 +/- 8.5 hours; group B, mean 29 +/- 85 hours), total blood loss (group A, mean 471 +/- 347 ml; group B, mean 543 +/- 404 ml), intensive care unit stay (group A, mean 1.2 +/- 0.6 days; group B, mean 2 +/- 3.7 days), and hospital stay (group A, mean 9.5 = 3.2 days; group B, mean 12 +/- 6 days). Postoperatively, all patients are in New York Heart Association class I (93%) or II (7%) (p = not significant). Ejection fraction for the two groups did not change significantly over the follow-up period. Left ventricular mass and diastolic diameter showed progressive regression, with no apparent difference between the two treatment groups to date. Echocardiographic evaluation of aortic valve function at 6 months showed good valve function in all patients with no evidence of aortic regurgitation in 80% of both groups. In group B the right ventricular outflow gradient was below 15 mm Hg over the follow-up period. Holter monitoring, available only in 44 patients (63%), showed most of the arrhythmias to be grade 0 to 1 of the modified Lown grading system.

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(3)安全性・信頼性

(4)患者 QOL

(5)コストベネフィット

特に記載なし

C、stentless xenografts と homografts の比較

stentless な異種移植片は、耐久性を強化し優れた血行力学性能を示すことが知られているが、同種移植片（homografts）と比較評価した 4 件の論文の内、対照強化電子ビームX線断層撮影で大動脈根壁のカルシュウムを定量化した結果、同種移植片でより多くの石灰化への傾向を示したとする論文が 2 件、大動脈弁置換後"Freestyle"(stentless 異種移植弁)では特に高い Transvalvular velocities を観測しなかったとするのが 1 件、生存率、心内膜炎、再手術では stentless が優れており血栓塞栓性イベントからの開放では僅かに劣るもののstentless を評価する論文が 1 件であった。なお、3 件の論文で異種移植片に Medtranic 社の"Freestyle"が採用されていた。

(1)技術摘要疾病

aortic valve diseases 4 件

(2)診断・治癒能力

文献No	評価結果	疾病名称	対比技術	治癒性
MED 4	△	aortic valve desease s	Medtronic Freestyle bioprosthe sis vs homograft s	At follow up, none of the patients showed high transvalvular or subvalvular velocities (>2 m/s). At six weeks after surgery the transvalvular velocity was 1.5+/-0.3 m/s in group H (n = 51) and 1.7+/-0.3 m/s in group F (n = 56) (p = NS), while subvalvular velocities were 0.9+/-0.3 and 1.0+/-0.3 m/s, respectively (p = NS). These findings remained constant up to the three-year follow up, when transvalvular velocity was 1.6+/-0.4 m/s in group H (n = 10) and 1.6+/-0.2 m/s in group F (n = 15) (p = NS
MED 5	○	aortic valve diseases	Freestyle xenograft vs homograft s	The aortic leaflets were clearly visualized in all patients. The mean calcium score in the cusps was 28.8+/-64.4 HU in group F and 62.4+/-66.9 HU in group H (p = not significant). The mean calcified volume score was 327.0+/-425.9 mm3 in group F and 642.0+/-443.0 mm3 in group H (p = not significant).
MED 12	○	aortic valve diseases	Unstented Freestyle valve vs homograft	Seventy-six patients (age range: 40-79 years) were randomized to root replacement with either homograft (n = 31) or Freestyle (n = 45) valves. Fifty-three scans of the aortic root were performed postoperatively in 37 patients. No statistical difference between the two groups was found at six and 12 months after surgery. However, after 18 months the calcified volume score was 5903.8+/-2356.8 mm3 in the homograft versus 2725.6+/-1500.5 mm3 in the Freestyle group (p = 0.017). There was a correlation between calcification score, calcified volume score and left ventricular mass (r = 0.323, p = 0.093 and r = 0.350, p = 0.068, respectively) on the one hand, and calcification score, calcified volume score and valve size on the other hand (r = 0.178, p = 0.466 and r = 0.068, p = 0.780, respectively
MED 18	○	aortic valve diseases	stentless xenograft vs pulmanar y homograft	There were 5 in-hospital deaths (3.5%): 4 HX and 1 SX (p = NS). The mean gradient was 6+/-2 mm Hg in HX versus 13+/-6 mm Hg in SX (p<0.001) and remained unchanged during follow-up. Actuarial survival (HX 77%, SX 80%), freedom from endocarditis (HX 91%, SX 99%), freedom from thromboembolic events (HX 98%, SX 90%), and freedom from reoperation (HX 98%, SX 100%) were comparable between groups after 58 months..

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(3)安全性・信頼性

(4)患者 QOL

(5)コストベネフィット

特に記載なし

D、機械式弁と生体弁の比較

機械式弁を生体弁と比較した15年間の臨床評価では、機械式弁の原発生故障は皆無であり、故障率や再手術は生体弁に多く、血栓塞栓症率は同等、寿命は機械式が短いとした論文が1件、大動脈弁挿入後脳内に起こる一時的信号（HITS）の発生は同種移植片の方が弱く回数

も少なく、有意前兆の解明が必要するものが 1 件、術後の早い段階と安定状態でのドップラー心エコーの測定は、弁機能障害が疑われた時など有益な情報を臨床医に与えるとしたものが 1 件、メタ分析で両者の長期での死亡率の違いはないが、僧帽弁・大動脈弁（5 年以後）、大動脈弁（11 年以後）で機械式の放出の危険性が確認されたとする論文が 1 件であった。

(1) 技術摘要疾病

aortic valve diseases 4 件、mitral valve diseases 1 件であった。

(2) 診断・治癒能力(

文献 No	評価結果	疾病名称	対比技術	治癒性
MED 9	○	valve diseases	bioprothetic vs mechanical valve	Primary valve failure occurred mainly in patients <65 years of age (bioprosthesis vs. mechanical, 26% vs. 0%, p < 0.001 for AVR and 44% vs. 4%, p = 0.0001 for MVR), and in patients > or =65 years after AVR, primary valve failure in bioprosthesis versus mechanical valve was 9 +/- 6% versus 0%, p = 0.16. Reoperation was significantly higher for bioprosthetic AVR (p = 0.004).
MED 22	×	aortic valve diseases	Homograft vs mechanical aortic valve	HITS were detected in more patients after implantation of a mechanical aortic valve prosthesis compared with a homograft aortic valve (16 versus 8, p=0.02). Nevertheless, more patients with a homograft aortic valve showed HITS than the control patients (8 versus 1, p=0.02). The mean number of HITS in the mechanical prosthesis group was higher than in the homograft group (3, range 0·18 versus 13, range 0·70, p<0.05). HITS in patients with mechanical prostheses had a higher amplitude than HITS in patients with homograft aortic valves (p<0.0001). Focal neurological deficit (FND) was diagnosed in 9 patients (mechanical prosthesis 6 versus homograft 3, ns).
MED 24	△	aortic valve diseases	biological aortic valves vs mechanical valve	The comparison of baseline with late investigation (mean +/- SD) showed an increase in systolic blood pressure (137 +/- 18.5 to 154 +/- 20.6 mm Hg, p = 0.0001, n = 11 2), reduction of heart rate (85 +/- 15.3 to 74 +/- 12.0 beats/min, p = 0.0001, n = 141) and increase in stroke volume (59 +/- 20.6 to 77 +/- 19.8 ml, p = 0.0001, n = 132). Prosthetic Doppler echocardiographic findings demonstrated a reduction in blood flow velocity in the left ventricular outflow tract (VLVOT, 1.10 +/- 0.25 to 0.96 +/- 0.23 m/sec, p = 0.0001, n = 146) reduction in peak velocity (Vmax 2.72 +/- 0.53 to 2.59 +/- 0.54 m/sec, p = 0.02, n = 150), reduction in mean pressure gradient (deltaPmean, 18.4 +/- 7.2 to 16.3 +/- 7.3 mm Hg, p = 0.004) and an increase in velocity index (Vmax/VLVOT, 2.56 +/- 0.62 to 2.67 +/- 0.60, p = 0.003, n = 144).
DARE 1	×	heart valve diseases	bioprothesis vs mechanical	Reoperation was significantly more frequent in patients with bioprostheses after 11-year follow-up (RR=0.4, 95% CI:0.28, 0.58, p <0.0001), although statistically-significant heterogeneity was found (p=0.059). Bleeding was more frequent in patients with mechanical prostheses, both after 5 years (RR=2.5, 95% CI:1.89, 3.49, p <0.0001) and 11 years (RR=1.65, 95% CI:1.25, 2.18,